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Re: President's Food Safety Council: Strategic Plan;
***Federal Register*, Vol. 64, No. 116 (June 17, 1999), pp. 32788-32790**

The Center for Science in the Public Interest (CSPI) appreciates this opportunity to provide comments on the Draft Food Safety Strategic Plan developed by the President's Council on Food Safety (the Council). CSPI is a nonprofit consumer group with over one million members in the United States and Canada that focuses primarily on nutrition and food-safety issues.

While the Council and its workgroups are to be applauded for their efforts to devise a national strategic plan for food safety, it is clear that public input earlier in the process could have dramatically improved the product. Dialogue with interested groups was not sought until after the basic framework was put in place and workgroups on specific elements of the plan had begun their deliberations. We have numerous concerns about the draft strategic plan and would like to see fundamental changes made to its basic framework. It is important that these changes not be rejected simply because the process has moved too far along for our suggestions to be given serious consideration by the Council.

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The draft strategic plan fails to communicate adequately with the public. The plan is not written so that it will be understood by consumers; instead, it is laden with overly complicated and bureaucratic language, and appears to have been drafted for an audience of Washington regulators and policy experts.

The draft strategic plan ignores the finding of the National Academy of Sciences. The plan fails to respond, as the administration said it would, to the findings and conclusions of the National Academy of Sciences (NAS) report "Ensuring Safe Food from Production to Consumption."[1] Most importantly, there is no attempt in the plan to create a food-safety system headed by "an identifiable, high-ranking, presidentially-appointed head, who would direct and coordinate federal activities and speak to the nation, giving federal food safety efforts a single voice," as called for by the NAS.[2]

The draft strategic plan fails to address the deficiencies in the current system that have been identified by CSPI and others. CSPI has documented numerous deficiencies in the existing system, as outlined in the attached Appendix. The General Accounting Office has also documented problems.[3] The final strategic plan should address and correct those deficiencies.

The Council should rewrite the strategic plan to provide a road map for the establishment of a single, independent agency responsible for ensuring the safety of *all* foods. At a recent congressional hearing on overlap and duplication in the federal food-safety system, Dr. Catherine Wotecki, Undersecretary for Food Safety, U.S. Department of Agriculture, testified that such a plan is still under consideration by the Council.[4]

The Council must recognize that a single, independent agency would provide the most rational and effective solution to the country's food-safety problems and would correct the myriad shortcomings in the existing, highly fragmented system. Such an agency is also the best way to establish a single voice and single budget for federal food-safety policy, as recommended by the NAS.

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[1] Institute of Medicine, National Research Council, *Ensuring Safe Food from Production to Consumption*, (Washington, D.C.: National Academy Press, 1998).

[2] *Ibid.*, p. 13.

[3] Testimony of Lawrence J. Dyckman, Director, Food and Agriculture Issues, U.S. General Accounting Office, before the U.S. Senate Subcommittee on Oversight of Government Management, Restructuring, and the District of Columbia, (August 4, 1999).

[4] Testimony of Catherine E. Wotecki, Ph.D., Undersecretary for Food Safety, U.S. Department of Agriculture, before the U.S. Senate Subcommittee on Oversight of Government Management, Restructuring, and the District of Columbia, (August 4, 1999).

CSPI urges the Council to replace its draft strategic plan with a new plan that better responds to the findings of the NAS, more clearly communicates the federal government's food-safety goals and objectives to the general public, and streamlines those goals and objectives into a more coherent and rational approach.

The revamped strategic plan should be based upon three primary activities:

- *Identification of food-safety risks.* This should include microbial, chemical, and physical risks. The tools for this include outbreak information from CDC and the states; illness information from FoodNet and PulseNet; and food contamination data from the agencies. The agencies should then do a risk assessment to identify the highest risk foods or processes.

- *Application of resources to control those risks.* The resouces available to combat foodborne illnesses include not only those at the federal level, but also state food-safety programs, industry programs, consumers, and the research community. The tools include the new HACCP systems, new food-safety technologies, inspection, sampling, performance standards, and consumer education. Hurdles to achieving a risk-based inspection system should be identified and addressed in this part of strategic planning. The most streamlined approach to managing these resources at the federal level is by forming a single, independent food safety agency.

- *Measurement of the public-health outcomes.* The tools are the same as those used to identify risks: outbreak information from CDC and the states, illness information from FoodNet and PulseNet; and food contamination data from the agencies. This should tie back into the risk assessment process and trigger the process of reallocating resources.

Those three activities clearly communicate to the public how the agencies are planning to create a risk-based food safety regulatory system. While many of the objectives described in the *Federal Register* strategic plan are important components of such a plan, they should be incorporated into a much clearer framework.

In addition to the general comments provided above, CSPI has several additional comments concerning the draft strategic plan.

- The draft strategic plan premises its actions on the overstated need for more food-safety data. "Goal 1" of the strategic plan, relating to the development and use of a food-safety knowledge base, reads like a prerequisite before action may be taken on the plan's other goals. This goal implies that the federal government lacks the necessary scientific knowledge to act on important food-safety issues. That is not true: an adequate knowledge base to address many pressing problems does exist,

and the objectives of Goal 1 should be folded into the plan's other goals as supplemental objectives, not prerequisites for action.

- Goal 3 mixes principles of risk assessment and risk management that should be treated separately by the food-safety regulatory system; by contrast, under the framework proposed by CSPI, risk assessment would occur under the "Identify Risks" prong, while risk management would take place during the second, "Apply Resources" prong.

- Goal 5 has as an objective "Enhance international understanding and acceptance of food safety standards that are in accordance with U.S. statutes and international trade agreements." To the extent that this objective focuses on international trade issues involving U.S. food products, it should not be part of the federal government's strategic plan for food safety.

- Ensuring the safety of imported foods, however, must be an objective of the strategic plan. The federal government should have the authority and resources necessary to audit foreign governments and inspect foreign food manufacturers that export foods to the U.S., to ensure that the food meets safety standards that are equivalent to those in this country.

The draft strategic plan of the President's Food Safety Council represents a modest advance down the same road that the administration has been on for some time. It protects the current structures, while promising better coordination. The Council needs to look "outside the box" to find the answers to the current food-safety problems. Otherwise, consumers will be asked to live with a system that reacts to -- rather than prevents -- food-safety problems.

Very truly yours,

Caroline Smith DeWaal
Director of Food Safety

Darren Mitchell
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Appendix

Under the current system, FDA is severely underfunded for its food-safety responsibilities. FDA's foods are generally, but erroneously, thought to pose a lower risk than the meat and poultry products regulated by USDA,[1] and Congress appropriates accordingly. FDA's budget for regulating foods is approximately one-third of USDA's food inspection budget.[2] In essence, FDA regulates more food with less money. FDA's food program also doesn't fare well when compared to other priorities at FDA. When you compare funding of the food program to that of the programs that approve drugs, biologics, and medical devices, the food-safety office at FDA only received 27% of the total program budget.[3] This is despite the fact that food represents more than 50% of FDA's mission area.[4]

Under the current structure, food-safety problems fall through the cracks of agency jurisdiction. Lettuce and other fresh vegetables and fruits are essentially unregulated for safety. Last year, FDA proposed a number of guidelines for farmers,[5] but they are entirely unenforceable. The use of animal manure on food crops is also not controlled. These are some of the problems that fall through the cracks of the current jurisdictional systems.

Under the current structure, multiple agencies fail to address glaring public health problems. Eggs are regulated both by FDA and USDA, but neither agency has developed an effective containment strategy to prevent the spread of *Salmonella enteritidis* (SE) in shell eggs. Instead, the agencies have acted like keystone cops, tripping over each other and bungling each attempt to control SE in eggs.[6] Today, over twelve years since SE inside eggs was first identified as a public-health concern by the Centers for Disease Control and Prevention, consumers still

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[1] Center for Science in the Public Interest, *Outbreak Alert! Closing the Gaps in Our Federal Food-Safety Net*, (Washington, D.C.: Center for Science in the Public Interest, Updated August 1999).

[2] U.S. Department of Agriculture, "U.S. Department of Agriculture 1999 Budget Summary," available at <http://www.usda.gov/agency/obpa...-Summary/1999/text.html#funding>Internet; U.S. Food and Drug Administration, "FY 2000 Budget Request Table of Contents," available at <http://www.fda.gov/oc/oms/ofm/budget/BudgetTOC.htm>Internet [hereinafter cited as *FDA Budget*].

[3] *FDA Budget.*

[4] *The FDA Food Additive Review Process: Backlog and Failure to Observe Statutory Deadline*, Fourth Report by the Committee on Government Reform and Oversight, December 21, 1995, p. 8.

[5] U.S. Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, *Guidance for Industry. Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*, (Washington, DC: U.S. Food and Drug Administration, October, 1998).

[6] U.S. General Accounting Office, *Food Safety and Quality: Salmonella Control Efforts Show Need for More Coordination*, (Washington, DC: U.S. General Accounting Office, April 1992).

await an effective strategy to eradicate SE in shell eggs.

Under the current structure, the same food-processing plant may get two entirely different food-safety inspections. The classic example is a processing plant that produces both pepperoni and cheese frozen pizzas. The pepperoni line will get daily visits from a USDA inspector to check on conditions in the plant as workers slice the pepperoni and apply it to the pizza.[7] The cheese line will be subject to FDA inspection on average once every 10 years.[8] The minimal difference in hazard between the processing of cheese and pepperoni pizzas is not enough to justify the vast disparity in government inspection. The recent memorandum of understanding (MOU) between USDA and FDA on inspection did nothing to address this disparity.[9]

Under the current structure, some food-processing plants may get no federal food-safety inspections. Due to resource constraints, FDA has turned some portions of its regulatory responsibility over to the states. The best example of this is in the area of shellfish production, where FDA relies totally on state inspections of shellfish packing houses. In other instances, FDA simply is unaware of plants that it is supposed to regulate. A 1991 Inspector General investigation documented that FDA's identifies food firms "by reviewing newspapers, magazines, phone books, industry publications, trade periodicals, surveillance reports and consumer complaints. Inspectors may also walk through stores looking for new products."[10] The Inspector General reported that, under this system, some food plants escape detection for long periods of time.

Under the current structure, quality inspections occur more frequently than safety inspections. There are many shell-egg plants that receive regular inspections from U.S. government inspectors, but the inspections are for quality, not for safety. All plants shipping eggs between states are visited by the Agricultural Marketing Service (AMS) each quarter and many plants also participate in a voluntary grading program where they receive continuous

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[7] Michael R. Taylor, "Preparing America's Food Safety System for the Twenty-First Century -- Who is Responsible for What When it Comes to Meeting the Food Safety Challenges of the Consumer-Driven Global Economy?" *Food and Drug Law Journal,* Vol. 52, No. 1 (1997), p. 18 [hereinafter cited as *Preparing for the Twenty-First Century*].

[8] U.S. Department of Agriculture, U.S. Department of Health and Human Services, U.S. Environmental Protection Agency, *Food Safety From Farm to Table: A National Food Safety Initiative. A Report to the President.* May 1997, p. 37 [hereinafter cited as *Food Safety from Farm to Table*], *Preparing for the Twenty-First Century*, p. 18.

[9] U.S. Department of Agriculture, Food Safety and Inspection Service, U.S. Department of Health and Human Services, Food and Drug Administration, *Memorandum of Understanding*, Feb. 23, 1999.

[10] Department of Health and Human Services, Office of the Inspector General, *FDA Food Safety Inspection*, August 1991.

inspection by AMS.[11] Under the voluntary AMS program, our government ensures that each has a yolk of the proper diameter, but nothing in the program checks for the presence of *Salmonella Enteritidis* (SE).[12] Nor does FDA, the agency charged with food-safety oversight of shell eggs, check for SE during its infrequent inspections.[13]

Under the current structure, HACCP is a different system at FDA and at USDA. The new HACCP systems for seafood, meat, and poultry share almost as many differences as similarities. For example, both frequent inspection and laboratory verification of product samples are essential to give the government appropriate oversight over plants utilizing HACCP. Otherwise, the HACCP program is little more than an industry honor system. While USDA requires both on-site inspection by government inspectors and two levels of laboratory verification of meat and poultry products, FDA requires neither for seafood products. FDA inspects seafood plants once every one to five years and made laboratory testing for HACCP verification optional for seafood processors.[14]

Multiple agencies may prolong the time it takes to bring the benefits of new technologies to the consumer. For example, last year, Agriculture Secretary Dan Glickman announced the commercial availability of a biological inoculation for young chicks against *Salmonella*.[15] This product was developed by the USDA's Agricultural Research Service and then spent years being considered for approval at the Food and Drug Administration.[16] For several other heralded technologies, like trisodium phosphate for poultry and irradiation for poultry and red meat, FDA approval is just the first step in implementation; there is often a public rulemaking process at USDA before products can be used in meat and poultry plants. This bifurcated process can take years to get through.[17]

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[11] 7 C.F.R. § 59.28; Poultry Division, AMS, USDA, "Quality Eggs for Volume Buyers," Brochure No. AMS-627, August, 1996.

[12] *Ibid.*

[13] Elizabeth Dahl and Caroline Smith DeWaal, *Scrambled Eggs: How a Broken Food Safety System Let Contaminated Eggs Become a National Food Poisoning Epidemic* (Washington, DC: Center for Science in the Public Interest, 1997), p. 11 [hereinafter cited as *Scrambled Eggs*].

[14] Caroline Smith DeWaal, "Delivering on HACCP's Promise to Improve Food Safety: A Comparison of Three HACCP Regulations," *Food and Drug Law Journal*, Vol. 52, No. 3 (1997), pp. 331-335.

[15] U.S. Department of Agriculture, "USDA Researchers Create New Product That Reduces *Salmonella* in Chickens," USDA Release No. 0121.98, March 19, 1998.

[16] Telephone conversation with John DeLoach, MS BioScience, Inc., Dundee, IL, April 1998.

[17] Rosanna Mentzer Morrison, Jean Buzby, and C. T. Jordan Lin, "Irradiating Ground Beef to Enhance Food Safety," *Food Review*, Vol. 20, No. 1 (1997), p. 34; U.S. Department of Health and Human Services, Food and Drug Administration, "Irradiation in the Production, Processing, and Handling of Food; Final Rules," *Federal*

Under the current structure, imported products are treated differently at FDA and USDA. Imported meat and poultry products are subject to a two-stage approval process by USDA. First, the exporting country's meat or poultry inspection safety system must be approved by USDA; then, the individual plant must be inspected by USDA before it can ship meat to the U.S. Even then, the meat is subject to random verification checks at the border. FDA meanwhile only has the authority to inspect food at the border but has the staff to check less than two percent of import shipments.[18] FDA can't send inspectors to foreign countries except by invitation, even when they are checking the source of food involved in an outbreak in the U.S.

Under the current structure, we risk exporting our irrational food-safety system. There is increasing international pressure to "harmonize" our food safety systems with the systems used in foreign countries. "Harmonization" is the process of assuring that the systems in use in foreign countries provide an equally safe food product.[19] With international trade in food products expanding rapidly, tremendous energy is being devoted to identifying and eliminating unnecessary barriers to trade and simplifying standard setting internationally, using organizations like Codex and the World Trade Organization.[20] We shouldn't harmonize internationally before we have harmonized our systems domestically, and this alone should provide some urgency to developing a more rational basis for our food safety system today.

Coordination with the state agencies that handle food safety is a nightmare. For example, state laboratories that analyze food samples for chemical or microbial contamination have complained about the lack of uniform testing methods and reporting requirements required by the federal agencies, including USDA, FDA, CDC, and the Environmental Protection Agency (EPA). This means that state labs may have to run multiple tests on a single food simply to meet the varying requirements of the federal agencies. In addition, they waste valuable staff time transmitting the same information to different agencies, which each have their own customized system for reporting lab results. The lack of common testing protocols and data requirements for

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Register, Vol. 62, No. 232 (1997), pp. 64102-64121; Memo from Robert Sindt, Burditt & Radzius, to Caroline Smith DeWaal, April 1, 1998; Meeting with Robert Sindt, Burditt & Radzius, James Elfstrum, Rhodia, and Jerry Carosella, Consultant, Regulatory Microbiology, Washington, D.C., April 3, 1998.

[18] U.S. General Accounting Office, "Food Safety: Federal Efforts to Ensure the Safety of Imported Foods are Inconsistent and Unreliable," (Washington, DC: U.S. General Accounting Office, April 1998), p. 5 [hereinafter cited as *Safety of Imported Foods*].

[19] *Agreement on the Application of Sanitary and Phytosanitary Measures,* Article 3, GATT Doc. MTN/FA II-A1A-4 (Dec. 15, 1993) in *Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations*, GATT Doc. MTN/FA (Dec. 15, 1993) 33 I.L.M. 9 (1994).

[20] *Preparing for the Twenty-First Century*, pp. 26-27.

foods discourages many states from sharing their laboratory data with the federal agencies.[21]

In addition, there are not common laboratory certification standards for state laboratories that test food for contamination. This means that in many outbreak and recall situations, a state lab test result will have to be repeated by a federal agency. This can result in a several day delay in recalling food or informing the public, with the continuing risk to public health.

Confusing food-safety standards exist because agencies can't agree. FDA and EPA have different public health standards for the permissible methylmercury content of fish. Methylmercury is a potent developmental toxin that accumulates in fish from environmental sources.[22] It can accumulate to toxic levels both in fresh water and ocean dwelling species. EPA has established a standard for recreationally caught fish that is more protective of public health than the standard that FDA applies to commercially caught fish. Efforts to set a single standard have resulted in a logjam, with Congress finally asking the National Research Council to mediate the squabble and set its own standard. Meanwhile, the public and the states are left to wonder what is the safe level for methylmercury in fish.

New technologies can completely escape government review for food safety, because of the complicated system of multiple reviews. For genetically modified foods, approval responsibilities for new plant varieties is done by three different federal agencies. USDA's Animal and Plant Health Inspection Service (APHIS) has a mandatory review process to protect against plant diseases and pests that might emerge from genetically modified seed stock. The EPA has a mandatory review process for genetically modified seeds with pesticidal qualities. FDA, meanwhile, utilizes a voluntary review process to address food-safety problems that might emerge from genetically modified foods. Under this system, FDA relies on an industry honor system that allows the biotech companies to decide whether and when they should consult with FDA prior to putting a product on the market.

This scheme certainly demonstrates that with respect to genetically modified foods, issues other than human-health issues have been the principle focus of government agencies so far. While every plant species using genetically modified techniques has to go through a review at APHIS to determine the impact on plant health, some of these species could escape any government review for food safety. Clearly, FDA has let resource deficiencies drive some policy issues. The agency simply has not had the staff to police emerging food issues properly. Given

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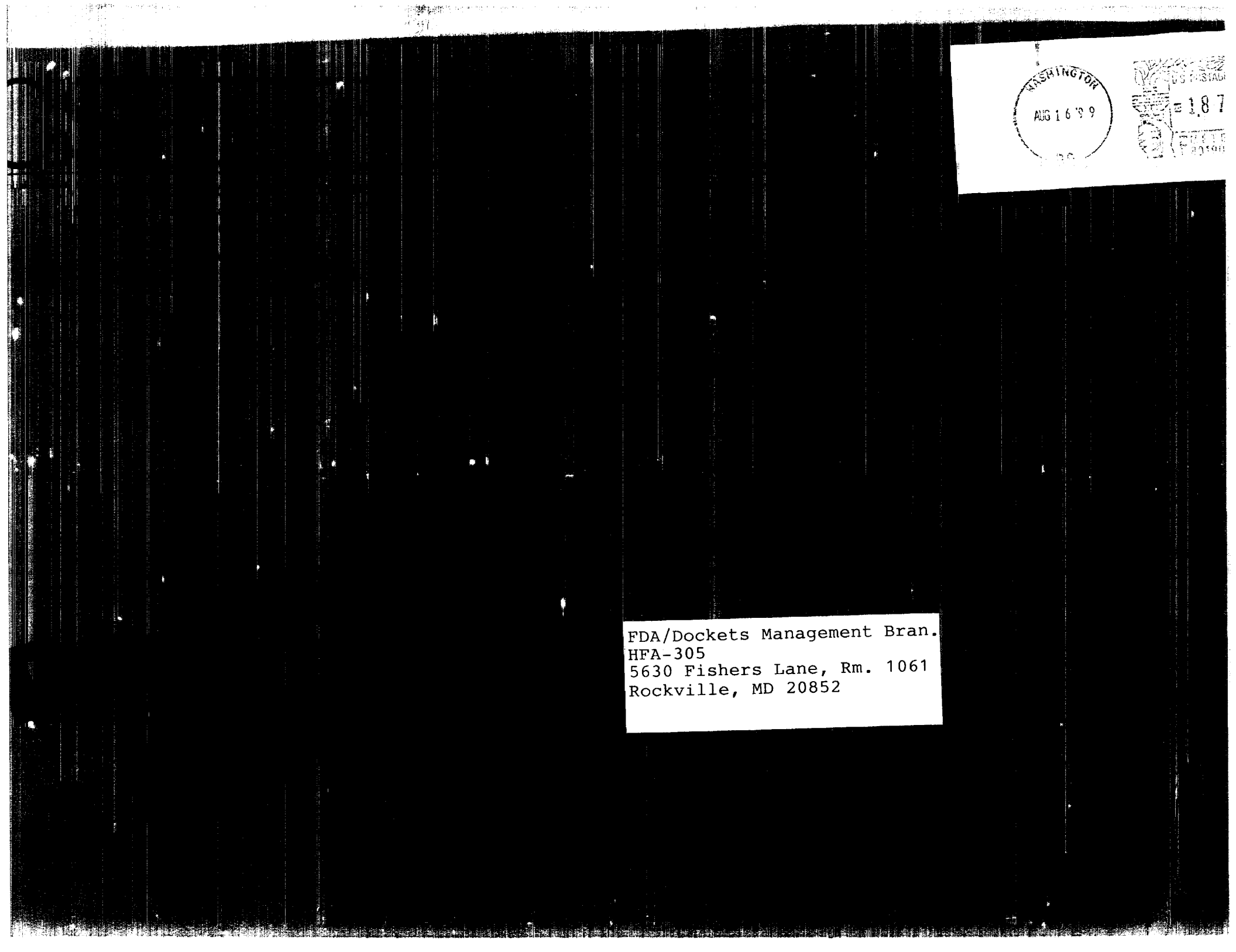
[21] "National Integrated Food Safety System. An Update on Work Group Activities: Laboratory Operations and Coordination," session at the 103rd Annual Educational Conference of the Association of Food and Drug Officials, June 5-9, 1999, San Antonio, TX; Association of Food and Drug Officials 1999 Resolution Number 99-09 Concerning National Standards for Computer-based Laboratory, Inspection and Surveillance Data Standards, June 7, 1999.

[22] Institute of Medicine, *Seafood Safety*, (Washington, DC: National Academy Press, 1991), pp. 12, 116-117.

FDA's other priorities, it is unclear if it ever will.



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